

CLAIMS

1. A composition in form of solution for use in an aerosol inhaler, the composition comprising an active material, a propellant containing a hydrofluoroalkane (HFA), a cosolvent, optionally a low volatility component wherein the propellant consists of a mixture of HFA 227 and HFA 134a in a range from 10:90 to 90:10 and the MMAD of the aerosol particles on actuation of the aerosol inhaler in use is not less than 2  $\mu$ m with the proviso that the active material is not cyclosporin-A.
2. A composition according to claim 1, wherein the low volatility component has a vapour pressure at 25°C lower than 0.1 kPa.
3. A composition according to claim 1 and 2, wherein the low volatility component has a vapour pressure at 25°C lower than 0.05 kPa.
4. A composition according to any preceding claim, wherein the cosolvent has a vapour pressure at 25°C lower than 3 kPa.
5. A composition according to any preceding claim, wherein the cosolvent has a vapour pressure at 25°C lower than 5 kPa.
6. A composition according to any preceding claim, wherein the cosolvent is an alcohol.
7. A composition according to any preceding claim, wherein the low volatility component includes a glycol, oleic acid or isopropyl myristate.
8. A composition according to any preceding claim, wherein the composition includes not more than 20% by weight of the low volatility component.
9. A composition according to any preceding claim, wherein the composition includes at least 0.2% by weight of the low volatility component.
10. An aerosol inhaler containing a solution composition comprising an

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active material, a propellant containing one or more hydrofluoroalkane, a cosolvent and optionally a low volatility component wherein the particle MMAD is greater than 2  $\mu\text{m}$  and the fine particle dose ( $< 4.7 \mu\text{m}$ ) is  $> 30\%$  with the proviso that the active material is not Cyclosporin A.

5 11. An aerosol inhaler according to claim 10 wherein the particle MMAD is greater than 2  $\mu\text{m}$  and the fine particle dose ( $< 4.7 \mu\text{m}$ ) is  $> 40\%$ .

12. An aerosol inhaler according to claims 10 and 11 wherein the particle MMAD is greater than 2  $\mu\text{m}$  and the fine particle dose ( $< 4.7 \mu\text{m}$ ) is  $> 50\%$ .

13. An aerosol inhaler according to claims 10 to 12 having a chamber volume ranging from 25 to 50  $\mu\text{l}$  yielding an increase of FPD compared to inhalers having chamber volumes larger than 50  $\mu\text{l}$ .

14. An aerosol inhaler according to claims 10 to 13 having part or all of the internal surfaces consisting of stainless steel, anodized aluminium or lined with an inert organic coating.

15. A delivery system for the administration of drugs to the lung consisting of aerosol drug solution in a mixture of 134a and 227 HFA propellants, a cosolvent and optionally a low volatility component, in an aerosol inhaler having a chamber volume ranging from 25 to 50  $\mu\text{m}$ , wherein the MMAD of the aerosol particles on actuation of the inhaler is not less than 2  $\mu\text{m}$  and the fine particle dose ( $< 4.7 \mu\text{m}$ ) is at least 30%.

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